UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,083	05/03/2001	Ute Heim	101195-48	8405

27387 7590 07/29/2004

BRUCE LONDA
NORRIS, MCLAUGHLIN & MARCUS, P.A.
220 EAST 42ND STREET, 30TH FLOOR
NEW YORK, NY 10017

EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,083	HEIM, UTE	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0202*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's responses to the election/restriction filed October 14, 2003, January 16, 2004 and April 8, 2004, and the preliminary amendment filed April 8, 2004, have been entered.

Claims 14-18 are cancelled.

Claims 1-13 and 19-23 are pending.

Claims 1, 3, 6-10, 13, 19, 21 and 22 are currently amended.

Applicant's election with traverse of Group I, claims 1-8, 12-13, 17 and 19 in the reply filed on October 14, 2003 is acknowledged. The traversal is on the ground(s) that the cited prior art of Heim et al. or Grimes et al. do not provide a the basis for asserting a lack of unity because neither discloses a sucrose binding protein (SBP) promoter sequence. Because Heim et al. or Grimes et al. do not disclose a SBP promoter sequence, and because all pending claims are directed to a single SBP promoter sequence of SEQ ID NO:1, the previous restriction requirement is withdrawn, and all pending claims are examined on the merits.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed February 14, 2002 is attached to the instant Office action.

The foreign patent document number 196 04 588 (8/1997 Germany) provided in the information disclosure statement filed February 14, 2002 fails to comply with 37 CFR 1.98(a)(3), because it is not in the English language, and a concise explanation of its relevance is not included. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claims 4, 7, 11-13 and 23 are objected to because of the following informalities: the acroymn "SBP" is recited without recitation of what is abbreviated in the claim itself or the claim from which it depends. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 11 and 12 are directed to a plasmid pSBPROCS and a plasmid pPTVBPRGUS. Claim 13 is directed to a method for inserting an expression cassette into a plant cell that requires

the use of clones VfSBP20 and pSBPR15, and the plasmid pSBPOCS, and claims 20-22 are directed to plants cells and plants produced by said method.

It is apparent that the plasmids pSBPROCS and pPTVBPRGUS and clones VfSBP20 and pSBPR15 are required to practice the claimed invention. As such they must be obtainable by a repeatable method set forth in the specification, or otherwise be known and readily available to the public. If these plasmids and clones are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof.

The specification does not disclose a repeatable process to obtain the exact same plasmid or clone in each occurrence, and it is not apparent if such plasmids and clones are known and readily available to the public. Therefore, a deposit at a recognized depository may be made for enablement purposes.

If the deposit of these plasmids and clones has been made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the plasmids and clones will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

For each deposit made pursuant to these regulations, the specification shall be amended to contain (see M.P.E.P. § 1.809):

(1) The accession number for the deposit;

(2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

Claims 1-10, 19 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated promoter DNA fragment obtained from *Vicia faba* that is a 1539 bp sequence 5' to the ATG of the *Vicia faba* sucrose binding protein (SBP) gene VfSBP20 in plasmid SBPR7, and an isolated promoter the DNA fragment obtained from *Vicia faba* that is a 1750 bp of sequence 5' to the ATG of the *Vicia faba* sucrose binding protein (SBP) gene VfSBP20 in plasmid SBPR15, as well as expression cassette, plasmids, plant cells and plants comprising said isolated promoter DNA fragments, does not reasonably provide

enablement for a promoter wherein there exists the sequence of SEQ ID NO:1 or a promoter according to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a promoter wherein there exists the sequence of SEQ ID NO:1, wherein said promoter mediates gene expression in cotyledons and endosperm . The claims are also drawn to an expression cassette containing a promoter according to SEQ ID NO:1, plasmids, plant cells and plants comprising said promoter, and a method for inserting said expression cassette into a plant cell.

SEQ 1 is disclosed in the sequence listing as a 1783 bp promoter polynucleotide obtained from *Vicia faba*. Figure 1 is disclosed at page 2 as being the sequence of SBP promoter, and a visual comparison of SEQ ID NO:1 and Figure 1 indicates that Figure 1 depicts SEQ ID NO:1. The specification does not characterize or otherwise make additional reference to SEQ ID NO:1.

The specification at page 6 discloses the cloning of a sucrose binding protein (SBP) gene from *Vicia faba* using primers derived from the sequence of a cDNA clone which codes for the SBP of soybean. The primers were used to isolate from immature cotyledons a *Vicia faba* cDNA (VfSBP20) that has 68% homology at the nucleotide sequence level to the soybean SBP cDNA sequence, and that differs from soybean in both is expression (Fig. 2a) and function (no sucrose binding).

The specification at page 7 discloses the cloning of two *Vicia faba* SBP regulatory sequences, a 1539 bp sequence 5' to the ATG of the *Vicia faba* SBP gene, and a 1750 bp sequence 5' to the ATG of the *Vicia faba* SBP gene. These two regulatory sequences were

cloned from the *Vicia faba* SBP gene using primers derived from the sequence of the *Vicia faba* SBP cDNA. These primers were used to isolate a fragment of 1.7 kb from *Vicia faba* ScaI digested genomic DNA, and a fragment of 1.9 kb from *Vicia faba* StuI digested genomic DNA. The ScaI and StuI fragments were cloned into pUC18 (to produce plasmids SBPR7 and SBPR15), sequenced, and found to represent allelic variants of the *Vicia faba* SBP gene, being 100% identical in an unspecified "corresponding area", and differing from each other by unidentified 23 base pair substitutions and two unspecified insertions. The specification does not disclose the sequence of these two DNA fragments, the sequence and location of the "corresponding area" in which they are 100% identical, the sequence and location of the 23 base pair substitutions, the sequence and location of two insertions, or in what way these two DNA fragments are related to the reference sequence of SEQ ID NO:1.

The specification at page 8 discloses that SalI/NcoI was used to isolate a promoter fragment from each of pSBPR7 and pSBPR15, and that each SalI/NcoI promoter fragment was cloned into the SmaI site of pBI101 in front of the GUS reporter gene, with plasmids pBISBPR7GUS and pBISBPR15GUS resulting. These plasmids were then used to transform tobacco, and analysis of the transgenic tobacco seeds showed a strong activity of the glucuronidase in the endosperm and in the cotyledons (Figures 2b and 2c).

The specification at page 8 also discloses that the SalI/NcoI promoter fragment of pSBPR15 was cloned into pGUS1 to produce pSBPGUS, and that the SBP15 promoter/GUS/ocs terminator expression cassette from pSPBGUS was cloned into pGPTV-Bar to produce pPTVSBPRGUS (figure 4), which was used to transform peas. The embryos of the transgenic

pea lines generated with pPTVSBPRGUS showed a strong blue coloration after a histo-chemical analysis.

The specification at pages 8-9 discloses that pSBPGUS was used to transform isolated embryos of *Vicia faba*, *Vicia narbonensis*, *Pisum sativum* and *Brassica napus*, and that unlike the negative control (promoter-free PGUSI), a number of blue dots were registered in the above mentioned embryos, showing that the *Vicia faba* SBP promoter functions in the seeds.

The specification at pages 8-9 discloses that the SalI fragment of SBPR15 was isolated and cloned into the SmaI site of POCSI to produce pSBPOCS, and that the BamHI fragment of the *Clostridium thermocellum* xylanase Z gene was then cloned into the BamHI site of pSBPOCS as a translational fusion to produce pSBPRXYNZ (Figure 6), which was used to transform tobacco. Strong expression of xylanse Z was observed in ripe seeds transformed with pSBPRXYNZ (Figure 7).

The full scope of the claimed invention is not enabled because it is unpredictable whether any polynucleotide obtained from *Vicia faba*, such as SEQ ID NO:1, would function as a promoter, or as a seed-specific promoter, because basal and tissue-specific promoter function requires the presence of specific nucleotides and nucleotide sequence motifs in the polynucleotide, which nucleotides and motifs may not be present in SEQ ID NO:1.

SEQ ID NO:1 may lack key nucleotides required for basal promoter function. See, for example, Kim et al. (Plant Molecular Biology, 1994, Vol. 24, pages 105-117), who teach that various point mutations in the nos promoter can alter the level of promoter activity in tobacco. Mutation of one or more key nucleotides in either of two hexamer motifs or in the octamer spacer region between them significantly altered the level of *nos* promoter activity (Table 2, page

109). A single point mutation in the sixth nucleotide of the hexamer motif resulted in a four to ten fold decrease in promoter activity, whereas a double point mutation in the fourth and fifth nucleotide of the hexamer motif resulted in a two-fold increase in promoter activity. Two independent triple point mutations in the third, fourth and fifth, and sixth, seventh and eighth nucleotides of the octamer spacer region eliminated detectable promoter activity.

SEQ ID NO:1 may also lack key nucleotide motifs required for tissue-specific promoter function. See, for example, de Pater et al. (The Plant Cell, August 1993, Vol. 5, pages 877-886), who teach that a 22 bp region located from nucleotide -56 to nucleotide -35 of the pea lectin promoter sequence contains three overlapping TGAC-like motifs that function to confer seed-specific gene expression to the promoter (page 877 abstract; page 879 Figure 2).

In the instant case Applicant has not provided guidance with respect to functionality of SEQ ID NO:1, or with respect to the identity and location of key nucleotides and regulatory regions required for basal or tissue-specific promoter function, in SEQ ID:1 or in the exemplified promoter fragments. Applicant also has not provided guidance with respect to the relatedness of SEQ ID NO:1 and the exemplified promoter fragments. Absent such guidance it would require undue experimentation for one skilled in the art to use a promoter of SEQ ID NO:1, as one skilled in the art would have to determine whether and what kind of promoter function SEQ ID NO:1 exhibits, and how to modify SEQ ID NO:1 to achieve the type of promoter function desired (general expression, or expression in cotyledons and in the endosperm of seeds as a function of development).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 5, 7, 8 and 13, and claims 20-22 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the expression" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 4, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 5 recites the limitation "the DNA region provided with a transcriptionally regulatory sequence for strong seed-specific gene expression" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the signal peptide of the SBP seed protein gene" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "the gene of the binding protein" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the expression cassette containing a DNA sequence for over-expression of genes in plant seeds" in part (e). There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the expression cassette containing an gene under the control of the promoter according to claim 1" in part (f). There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 and 23 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-12 and 23, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" or "recombinant". See MPEP 2105.

Remarks

No claim is allowed.

Claims 1-13 and 19-23 are deemed free of the prior art due to the failure of the prior art to teach or suggest a polynucleotide comprising SEQ ID NO:1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins Cynthia Collins 7/26/04